FDA 510(k) Premarket Notification

K182737 3T 32 Channel Head Coil

CLEARED

Apr 12, 2019
196 days to decision

K182737 · Product code: **MOS** · Radiology
Source: https://www.510kdatabase.net/k182737/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Sep 28, 2018
Decision date	Apr 12, 2019
Days to decision	196 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Nova Medical, Inc.**
Location	Wilmington, MA, US
Contact	Cheryl Ledden
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**Emergo Global Consulting, LLC**
Contact	Julie Powell

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov